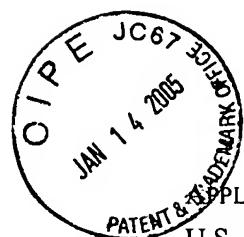


Express Mail Label No.: EV399524534US  
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1/18/05  
1/18/05  
Attorney Docket No.: 28142-501 UTIL  
(formerly 59533(49397))



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Pace and Smith CONFIRMATION NO.: 7151  
U.S. SERIAL NO. : 10/661,458 CUSTOMER NO.: 35437  
FILED : September 10, 2003  
TC/A.U. : 1614  
EXAMINER : Not Yet Assigned  
FOR : Methods and Compositions for Reducing the Risk Associated With  
the Administration of Opioid Analgesics in Patients With Diagnosed  
or Undiagnosed Respiratory Illness

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the non-patent literature documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-identified application. Accordingly, no fee or certification is believed to be required.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims. It is also respectfully requested that the Examiner initial, sign and date, and return a copy of the signed modified Form PTO-1449 with the next U.S. PTO communication, to evidence that the cited information has been fully considered by the U.S. Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the

information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

The order of presentation of the references should not be construed as an indication of the importance of the references. The Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

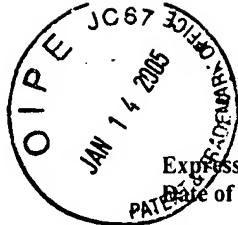
Please charge any fees that may be due to Deposit Account No. 50-0311, Reference No. 28142-501 UTIL, Customer No. 35437.

Respectfully submitted,

  
\_\_\_\_\_  
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PTO/SB (12-97)  
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Modified Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/661,458
		Filing Date	09/10/03
		First Named Inventor	Pace
		Group Art Unit	1614
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	28142-501 UTIL

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
	A1	4,522,811	06/11/85	Eppstein et al.			07/08/82
	A2	5,508,042	04/16/96	Oshlack et al.			06/06/95
	A3	5,549,912	08/27/96	Oshlack et al.			11/25/92
	A4	6,310,072	10/30/01	Smith et al.			08/29/97

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Beaver et al. (1978). <i>J. Pharmacol. Exp. Ther.</i> 207: 92-100.
	C2	Cherny and Portenoy, "Practical Issues In the Management of Cancer Pain" in <i>Textbook of Pain</i> , 3 <sup>rd</sup> ed., eds. Wall and Melzack, Churchill and Livingstone, pages 1437-1467.
	C3	Du Bose and Berde, Technical Corner, <i>International Association for the Study of Pain Newsletter</i> , July/August 1997.
	C4	Farney et al. (2003). <i>Chest</i> 123: 632-639.
	C5	Jaffe and Martin, "Opioid Analgesics and Antagonists" in <i>Goodman and Gilman's The Pharmacological Basis of Therapeutics</i> , Macmillan Publishing Co., Inc., pages 494-534.
	C6	Twycross, R.G., "Opioids" in <i>Textbook of Pain</i> , 3 <sup>rd</sup> ed., eds. Wall and Melzack, Churchill and Livingstone, pages 943-962.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Attorney Docket No.: **28142-501 UTIL**  
(formerly: 59533(49397))

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I hereby certify that the document(s) and/or fee(s) listed below are being deposited with the United States Patent and Trademark Office as Express Mail bearing Express Mail Label No. **EV 399524534 US** under 37 C.F.R. §1.10 in an envelope with prepaid postage on the date indicated above and addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

1. Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (1 page), in duplicate;
3. Cited References C1-C6;
4. Express Mail Transmittal (1 page), in duplicate; and
5. Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room is respectfully requested to contact the undersigned collect at (212) 935-3000, New York, New York. The Director is authorized to credit any overpayment or charge any deficiencies to Deposit Account No. **50-0311**, Reference No. **28142-501 UTIL**, Customer No. **35437**.

Dated: **January 14, 2005**

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